510(k) Summary
21 CFR 807.92

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
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Official contact: Michael Davis, Regulatory Affairs Manager
Date prepared: November 4, 2011

Name of the Device

Trade Name: BioHorizons Abutments for Zimmer®
Common or Usual Name: Dental implant abutment
Classification Name: Endosseous dental implant abutment
Classification Number: Class II (21 CFR 872.3630)

Predicate Devices

1. BioHorizons Simple Solutions with Laser-Lok, documented under 510(k) number K100985, concurrence date September 9, 2010.
2. BioHorizons Internal Implant System, documented under 510(k) number K073268, concurrence date of February 8, 2008.
3. BioHorizons Tapered Internal Implant System, documented under 510(k) number K071638, concurrence date of October 10, 2007.
4. Zimmer® Dental (formerly Sulzer Dental) Screw-Vent® and Tapered Screw-Vent® systems, documented under 510(k) number K013227, concurrence date of November 19, 2001.
5. Zimmer Dental Ti Prepable Abutment, documented under 510(k) number K092403, concurrence date of October 30, 2009.
6. Altatec GmbH CAMLOG Implant System Abutments, documented under 510(k) number K073553, concurrence date of March 5, 2008.
7. Neoss Ltd. various Titanium Abutments, documented under 510(k) number K071838, concurrence date of October 19, 2007.
8. Altatec GmbH CAMLOG Implant System Modified Implants and Abutments, documented under 510(k) number K083496, concurrence date of January 30, 2009.
9. Sirona Dental CAD/CAM System, documented under 501(k) number K100152, concurrence date of October 22, 2010.
10. Thommen Medical AG SPI Titanium Base for CAD/CAM, documented under 510(k) number K102804, concurrence date of April 20, 2011.

Device Description

BioHorizons Abutments for Zimmer® are comprised of endosseous dental implant healing abutments and final restorative abutments supplied in platform diameters of 3.5mm, 4.5mm and 5.7mm. Abutment materials are titanium alloy as specified in ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401),* zirconia ceramic as specified in ISO 13356 *Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP),* Gold Alloy 6019 and PEEK as specified in ASTM

F2026 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications* (temporary abutments only).

Select abutments are further processed by applying patterns of micro-machined grooves or channels, known as Laser-Lok, to a specified portion of the abutment margin. Abutments provided sterile are packaged using materials known in the industry to be appropriate for medical device packaging and are provided with a minimum sterility assurance level of 10^{-6}, validated in compliance with ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ANSI/AAMI/ISO 11137-2 *Sterilization of healthcare products -- Radiation -- Part 2: Establishing the sterilization dose.*

Intended Use

BioHorizons Abutments for Zimmer® are abutments that include healing abutments for contouring tissue and final restorative abutments to support a prosthesis. The abutments may be used for a single or multiple unit restoration and are compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer® Dental Screw-Vent® and Tapered Screw-Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters.

BioHorizons Titanium Base Abutments and Laser-Lok Titanium Base Abutments are intended to be used as straight abutments.

Compatibility Testing

Compatibility testing was performed on a representative subset of Zimmer® Screw-Vent® and Tapered Screw-Vent® implants. The subset included the following Zimmer® item numbers: TSVB8, TSV4B11, TSV4B13, TSVH13, TSV4H10, TSV4H11, TSV4H16, TSVWH10, TSVWH11, TSVWH13, TSVWH16, TSV6B8, TSV6H8, TSV6H10, TSV6H11 and TSV6H13. This testing verifies compatibility of BioHorizons Abutments for Zimmer® with all Zimmer® Screw-Vent® and Tapered Screw-Vent® items listed in the following table based on equivalent mating platform geometry.

Platform	Zimmer® Tapered Screw-Vent® Implants*	Zimmer® Screw-Vent® Implants*
3.5mm Internal Connection	TSVBx TSV4Bx TSVHx TSV4Hx	SVMBx SVBx SVMHx SVHx
4.5mm Internal Connection	TSVWBx TSVWHx	SVWBx SVWHx
5.7mm Internal Connection	TSV6Bx TSV6Hx	N/A

* Where variable x = implant length

Technological Characteristics

The fundamental scientific technology of the BioHorizons Abutments for Zimmer® is substantially equivalent to the existing abutments that are designed to mate with the implant components of the referenced predicate devices. Select devices are further processed by applying Laser-Lok to a specified region of the abutment margin.

Laser-Lok is a surface feature in which patterns of micro-machined grooves are applied to the abutment margin, providing a roughened surface to establish a physical, connective tissue attachment (unlike Sharpey fiber attachment). This tissue connection:

1) is functionally oriented,
2) inhibits epithelial cell downgrowth and
3) enables crestal bone attachment adjacent to the implant.

All materials, suppliers, processing, packaging and sterilization methods remain the same as those utilized for the predicate BioHorizons implant systems (K073268 and K071638), and the Laser-Lok feature is substantially equivalent to that cleared for the BioHorizons Simple Solutions with Laser-Lok (K100985). The BioHorizons Abutments for Zimmer®, which are the subject of this 510(k), are substantially equivalent to all features of the predicate abutment and implant devices which could affect safety or effectiveness because of the similarities in design, materials and intended use.

Summary of Testing

In addition to the compatibility testing described previously, the data presented in this 510(k) submission supports the substantial equivalence of the BioHorizons Abutments for Zimmer® to the specified predicate devices with respect to performance, safety and effectiveness. A prospective study was conducted in a canine model to evaluate bone and soft tissue healing patterns when Laser-Lok microgrooves are applied to dental implant abutments. The study consisted of four cohorts – Group A: Laser-Lok healing abutment on an RBT implant; Group B: Laser-Lok healing abutment on an RBT implant with a machined area; Group C: Machined healing abutment on an RBT implant; and Group D: Machined healing abutment on an RBT implant with a machined area. Laser-Lok and machined-surface healing abutments were randomly assigned to internal-connection implants that were either fully RBT-treated or RBT-treated with a 0.3mm machined collar. Each group received nine implants with abutments placed at the time of surgery. The results demonstrate significant improvement in peri-implant hard and soft tissue healing on the Laser-Lok healing abutments as compared to traditional machined abutment surfaces.

Nevins *et al* concluded that the presence of the laser-ablated microchanneled zone consistently enabled intense fibroblastic activity to occur on the abutment-grooved surface, resulting in an interlacing complex of connective tissue fibers oriented perpendicular to the abutment surface that served as a physiologic barrier to apical JE migration.

Mechanical testing has been performed on the subject devices in accordance with the Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004 and ISO 14801. The results of the maximum load and fatigue load testing demonstrate that the subject devices are substantially equivalent to the predicate devices.

Conclusion

The clinical and nonclinical data presented in this submission indicates that the new devices are safe and effective for their intended use and perform as well or better than the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 8 2011

BioHorizons Implant Systems, Inc.
Michael Davis
Regulatory Affairs Manager
2300 Riverchase Center
Birmingham, AL 35244

Re: K103691
Trade/Device Name: BioHorizons Abutments for Zimmer
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 30, 2011
Received: July 1, 2011

Dear Mr. Davis:

This letter corrects our substantially equivalent letter of November 3, 2011

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K103691

Device Name: BioHorizons Abutments for Zimmer®

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103691